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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,739	12/01/2000	Mark A. Sheridan	255.0004	4181

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EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/28/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N		Applicant(s)	
	09/727,739		SHERIDAN ET AL.	
	Examiner		Art Unit	
	Ruixiang Li		1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 5-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12 and 13 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

1. Applicants' election with traverse of Group I (Claims 1-3 and 12-15), drawn to somatostatin polypeptides, which directed to the amino acid sequence of SEQ ID NO: 15, in Paper No. 18 is acknowledged. The traversal is on the grounds (i) that the claimed inventions can be readily evaluated in one search without placing undue burden on the office; (ii) that claims 1-15 are generic, as each of the claims includes within its scope more than one species; and (iii) SEQ ID NO: 18 is a fragment of SEQ ID NO: 15. The arguments (i) and (ii) are not found persuasive because each individual sequence represents a structural and functionally distinct entity that is capable of supporting a separate patent. The search and consideration of more than a single sequence constitutes an undue search burden on the office, given the ever-increasing size of the database. In view of applicants' argument (iii), SEQ ID NO: 18 will also be searched and considered.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicants' amendment in Paper No. 5, 6, 15, and 18 has been entered in full. Claims 1 and 12 have been amended. Claims 1-3 and 12-15 are pending and under consideration.

Priority

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to a provisional application, 60/168,934, filed upon December 1, 1999.

Drawings

4. The drawings filed upon 12/01/2000 are accepted by the examiner.

Objection to the Disclosure

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (See, e.g., page 12, lines 25 and 30; page 15, line 21). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Rejections—35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, a somatostatin polypeptide or bioactive analog or subunit thereof. Since a somatostatin polypeptide or bioactive analog can be found in nature, the claims read on a product of nature. Products of nature do not constitute statutory subject matter. It is suggested that the word "isolated or purified" be used in the claims to modify the claimed molecules.

Claim Rejections—35 USC § 112, 1st paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides or fusion proteins comprising SEQ ID NOS: 15, 16, and 18, does not reasonably provide enablement for any other somatostatin polypeptides or fusion proteins comprising a portion of SEQ ID NO: 15. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 1 recites a genus of the somatostatin polypeptides comprising a portion of SEQ ID NO: 15, whereas Claims 12 and 13 recite a genus of fusion polypeptides comprising a portion of SEQ ID NO: 15. However, other than SEQ ID NO: 15 and its major fragments set forth in SEQ ID NOS: 16 and 18, the disclosure fails to provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant

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claims. The disclosure has not shown (i) which portions of SEQ ID NO: 15 are critical to the activity of the claimed polypeptide; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 15 will result in protein mutants with the same functions as the protein of SEQ ID NO: 15. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein.

Accordingly, the disclosure fails to enable such a myriad of the claimed somatostatin polypeptides and fusion polypeptides that vary substantially not only in length but also in amino acid composition and fails to provide any guidance to those skilled generally on how to use the claimed genus of molecules. Thus, it would require undue experimentation for one skilled in the art to use the claimed genus of molecules embraced by the instant claim.

Claim Rejections—35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Moore et al. (*IDS*, General and Comparative Endocrinology, 98:253-261, 1995).

Moore et al. teach a somatostatin polypeptide of preprosomatostatin II (See, e.g., Abstract and Fig. 2), which is a bioactive analog of SEQ ID NO: 15 and shares 79.7% sequence identity with SEQ ID NO: 15 (See attached sequence alignment), thus meeting the limitations of Claims 1 and 2.

Claim Rejections—35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al. (*IDS*, General and Comparative Endocrinology, 98:253-261, 1995), as applied to Claims 1 and 2, in view of Hobart et al. (EU 46669 A1, march 3, 1982).

Moore et al. teach preprosomatostatin II comprising with somatostatin-14 at the C-terminal region (See, e.g., Abstract and Fig. 2), as discussed above. Moore et al. fail to teach a fusion somatostatin polypeptide.

Hobart et al. teach a method for making a fusion protein comprising the amino acid sequence of a somatostatin or a somatostatin precursor as its C-terminal region (See, e.g, page 3, last but one paragraph).

Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce a fusion protein comprising an N-terminal somatostatin region covalently linked to a C-terminal region comprising the somatostatin-14 with a reasonable expectation of success. One would have been motivated to do so because the somatostatin-14 has been shown to have important physiological functions (See, e.g., page 253).

Claim Objections—Minor Informalities

14. Claims 1-3 and 12-15 are objected to because each claim recites an unelected subject matter (amino acid sequence). Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a

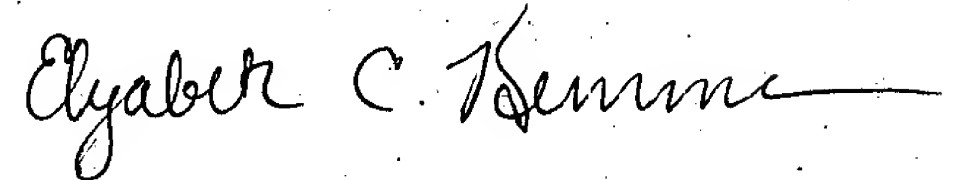
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possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
June 23, 2002



ELIZABETH KEMMERER
PRIMARY EXAMINER